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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/764,222	01/23/2004	Jack I. Shugart	506401-0059	9135

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EXAMINER

ROYDS, LESLIE A

ART UNIT	PAPER NUMBER
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1614

DATE MAILED: 02/09/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/764,222	SHUGART, JACK I.	
	Examiner	Art Unit	
	Leslie A. Royds	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 November 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-19 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-19 is/are rejected.
- 7) ☒ Claim(s) 2 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 1-19 are presented for examination.

Applicant's Amendment filed November 28, 2005 has been received and entered into the application. Accordingly, claims 2-12 have been amended.

In view of the above amendments and the remarks made herein, the objection to claims 3-12 for lack of antecedent basis and the rejection of claims 8-12 under 35 U.S.C. 112, second paragraph, are each hereby **withdrawn**.

Objection to the Claims

Applicant's amendment to claim 2 adding the limitation "and said composition is aversive when ingested or inhaled" has been noted, but fails to obviate the present objection. Such a limitation amounts to no more than a statement of the function of the composition and fails to limit the composition in any material or physical way such that the composition results in a physical or structural difference from the composition of claim 1. As a result, the objection remains proper because the limitations recited in claim 2 fail to further limit the subject matter of claim 1 and the claim, therefore, is still in improper dependent form. In light of the fact that Applicant has failed to overcome the objection, the objection as set forth previously at page 2 of the prior Office Action dated August 19, 2005 is repeated below.

Claim 2 remains objected to under 37 C.F.R. 1.75(c) as being of improper dependent form for failing to further limit, either physically or materially, the subject matter of the composition recited in previous claim 1. The recitation of "wherein said animal is a person and said composition is aversive to a person when ingested or inhaled" is merely a recitation of the

Art Unit: 1614

host in whom the function of rendering the composition aversive to an animal when ingested or inhaled would be accomplished or is a recitation of the function of the composition itself when administered to a host. Thus, such a limitation amounts to no more than a recitation of the intended use or ultimate function of the composition and fails to impart any physical or otherwise material limitation to the composition of claim 1 that is not already present.

Claim Rejection - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-19 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Sawyer et al. (U.S. Patent No. 5,290,775; 1994) in view of Baker (U.S. Patent No. 5,720,951; 1998), Oshlack et al. (U.S. Patent Application Publication 2003/0064099; April 2003), Minkoff (U.S. Patent No. 4,005,038; 1977), Komer (U.S. Patent No. 5,962,536; 1999) and Sawyer et al. (U.S. Patent No. 5,281,611; 1994), each already of record, for the reasons of record set forth at pages 4-9 of the previous Office Action dated August 19, 2005.

Applicant states that Sawyer '775, Komer and Sawyer '611 do not disclose or suggest an injectable euthanasia formulation containing a taste aversive agent and Baker, Oshlack or Minkoff do not disclose a euthanasia solution. Applicant submits that there is no suggestion or motivation from the cited references to incorporate the taste aversive substance from Baker,

Art Unit: 1614

Oshlack or Minkoff into the euthanasia solution of Sawyer '775, Komer or Sawyer '611 and that there is no suggestion or motivation from the cited references that a taste aversive agent would be chemically compatible with the chemicals in an injectable euthanasia solution. Applicant further states that one of ordinary skill in the art would not find such an addition to be obvious in view of the fact that numerous chemicals are not compatible with euthanasia formulations. Applicant submits that one of ordinary skill in the art would not assume that a taste aversive agent could be added to a euthanasia formulation to create an injectable euthanasia composition. Applicant further submits that neither Baker, Minkoff nor Oshlack provide motivation to incorporate a taste aversive agent into a formulation intended for injection and states that Oshlack actually teaches away from an injectable formulation.

Applicant's amendments and remarks have each been carefully considered in their entirety, but fail to be persuasive in establishing error in the propriety of the present rejection.

First, Applicant's arguments and discussion of the references individually has been noted, but Applicant fails to clearly address the combined teachings. It must be remembered that the references are relied upon in combination and are not meant to be considered separately as in a vacuum. It is the combination of all of the cited and relied upon references that make up the state of the art with regard to the claimed invention. Applicant's claimed invention fails to patentably distinguish over the state of the art represented by the cited references. See *In re Young*, 403 F.2d 754, 159 USPQ 725 (CCPA 1968) and *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981).

Although Applicant states on the record that Sawyer '775, Komer and Sawyer '611 do not disclose or suggest an injectable euthanasia formulation containing a taste aversive agent and

Art Unit: 1614

Baker, Oshlack or Minkoff do not disclose a euthanasia solution, such comments are not considered persuasive because they fail to clearly address the references as they were combined in the rejection at pages 4-9 of the previous Office Action dated August 19, 2005. Furthermore, it is noted that not one of the cited references of Sawyer '775, Komer, Sawyer '611, Baker, Oshlack et al. or Minkoff were relied upon to teach the presently claimed invention in its entirety. Rather, each of the references was cited *in combination* to show that the presently claimed invention would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention.

In response to Applicant's argument that there is no suggestion or motivation to incorporate the taste aversive substance from Baker, Oshlack or Minkoff into the euthanasia solution of Sawyer '775, Komer or Sawyer '611, the Examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992).

In this case, motivation to include a taste aversive agent into the euthanasia solution of resulting from the combination of Sawyer '775, Komer or Sawyer '611 was provided at page 6 of the previous Office Action dated August 19, 2005. Applicant's attention is directed thereto. One of ordinary skill in the art would have been motivated to employ a bittering agent such as denatonium benzoate in the euthanasia formulation primarily taught by Sawyer in order to deter human consumption of the toxic composition by eliciting an unpleasant, bitter taste upon

Art Unit: 1614

ingestion to protect those mammals that were not the intended recipients of such a composition or to deter abuse of such a composition. Baker, Oshlack and Minkoff were cited to show that denatonium benzoate was commonly used in the art as a bittering agent for the purposes of discouraging human consumption of toxic or commonly abused therapeutic agents. While it is noted that Baker, Oshlack or Minkoff do not expressly teach a euthanasia formulation, the teachings of such references raise the reasonable expectation of success that the inclusion of a known bittering agent, such as denatonium benzoate, into the euthanasia formulation primarily taught by Sawyer would have elicited a sufficiently unpleasant taste so as to deter inappropriate consumption of the formulation.

Applicant's assertion that there is no suggestion or motivation from the cited references that a taste aversive agent would be chemically compatible with the chemicals in an injectable euthanasia solution has been carefully considered, but amounts to no more than a general allegation of counsel and fails to be substantiated by any sound reasoning or evidence. Such a comment is, therefore, not considered at all persuasive.

Similarly, Applicant's assertion that one of ordinary skill in the art would not find the addition of a taste aversive agent, such as denatonium benzoate, to the euthanasia formulation primarily taught by Sawyer, obvious because numerous chemicals are not compatible with euthanasia formulations is also not found persuasive. Again, this is a general allegation of counsel and is not substantiated with any sound reasoning or scientific evidence demonstrating that the state of the prior art was such at the time of the invention that the skilled artisan would not have been motivated to include such an aversive agent (i.e., denatonium benzoate) because it would have been obvious that it was not compatible with a euthanasia formulation.

Art Unit: 1614

Insofar as Applicant has again failed to support the argument that one of ordinary skill in the art would not assume that a taste aversive agent could be added to a euthanasia formulation to create an injectable composition with any scientific reasoning or evidence, such remarks have been identified as arguments of counsel and are not found persuasive.

The assertion that Baker, Minkoff or Oshlack fail to provide sufficient motivation to incorporate a taste aversive agent into a formulation intended for injection is not a point well taken. It appears that Applicant has not considered the teachings of the references as a whole. Applicant's attention is directed to the previous Office Action at page 6. Baker teaches the use of the bittering agent denatonium benzoate or another salt of the denatonium cation in rodenticide bait, in order to deter human consumption of the bait, which is toxic to humans (see Baker, col.5, lines 16-21). Oshlack et al. teaches the use of denatonium benzoate as a bittering agent that may be incorporated into dosage forms containing commonly abused therapeutic agents, i.e., opioid analgesics, in order to discourage an abuser from tampering with and attempting to swallow or inhale the dosage form (see Oshlack et al., paragraphs [0021], [0038] and [0044]). Minkoff teaches the use of denatonium benzoate in a coating composition to be applied over previously coated surfaces, such as the interior surfaces of older dwellings, wherein the paint contained lead and other toxic substances, to deter anyone who may try to chew, suck, lick or eat the dried paint film by rendering the coating repulsive in taste (see Minkoff, col.2, lines 9-30 and col.3, lines 19-24).

The teachings of Baker, Minkoff or Oshlack et al. provide sufficient motivation to one of ordinary skill in the art to use a bittering agent, such as denatonium benzoate, in a composition known to be highly toxic to humans (i.e., a composition that induces euthanasia) in order to deter

Art Unit: 1614

consumption of such a composition and thereby avoid any adverse effects or fatality that would result from consumption. The mere fact that Baker, Minkoff or Oshlack et al. are not expressly directed towards a euthanasia formulation does not constitute a teaching away from the broader teachings of the reference, namely, the use of denatonium benzoate for discouraging human consumption of toxic compositions.

Applicant's argument that Oshlack et al. actually teaches away from the injectable composition of the present invention has been fully considered, but is also not found to be persuasive. Applicant relies upon Oshlack et al. at paragraph 41 in support of this argument. However, it appears that Applicant has focused only on the portion of the reference that supports this assertion, but has failed to consider the reference as a whole.

In further response to this argument, Applicant's attention is directed to Oshlack et al. at paragraph [0021], which states, "In certain embodiments of the present invention, the dosage form comprises an aversive agent such as a bittering agent to discourage an abuser from tampering with the dosage form and thereafter inhaling or swallowing tampered dosage form. Preferably, the bittering agent is released when the dosage form is tampered with and provides an unpleasant taste to the abuser upon inhalation and/or swallowing of the tampered dosage form."

Applicant is reminded that the disclosure of a reference is not limited only to that which is preferred. Applicant is directed to the MPEP at §2123, which states, "A reference may be relied upon for all that it would have reasonably suggested to one having ordinary skill in the art, including non-preferred embodiments...Disclosed examples and preferred embodiments do not constitute a teaching away from a broader disclosure or non-preferred embodiments." Thus, in the present case, while the invention of Oshlack et al. may preferably embody an oral dosage

Art Unit: 1614

form, such does not teach away from the broader disclosure of the reference, which teaches a dosage form, in general, in which a bittering agent is included to provide an unpleasant taste when ingested or inhaled. Such a teaching is expressly relevant to the presently claimed subject matter and does not, in any way, constitute a teaching away.

For these reasons above and those already made of record at pages 4-9 of the previous Office Action dated August 19, 2005, the rejection remains proper and is **maintained**.

Conclusion

Rejection of claims 1-19 remains proper and is **maintained**.

No claims of the present application are allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

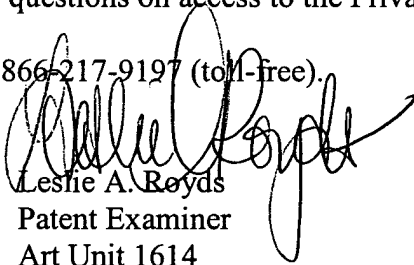
A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Art Unit: 1614

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leslie A. Royds whose telephone number is (571)-272-6096. The examiner can normally be reached on Monday-Friday (8:30 AM-5:00 PM).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on (571)-272-0951. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Leslie A. Royds
Patent Examiner
Art Unit 1614

February 2, 2006



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